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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,750	04/17/2001	James P. Elia	1000-10-C01	7239

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EXAMINER
KEMMERER, ELIZABETH

ART UNIT	PAPER NUMBER
1646	8

DATE MAILED: 08/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/836,750	ELIA, JAMES P.	
	Examiner	Art Unit	
	Elizabeth C. Kemmerer, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-235* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *6-235* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

The amendment filed 01 July 2003 (Paper No. 7) has been entered in full. It is noted that the amendment refers to two declarations filed under 37 CFR 1.132; however, these declarations were not attached to the amendment and could not be found in the file. The second supplemental IDS (Paper No. 6) submitted with the response has been received. Claims 1-5 are canceled. Claims 7-253 are pending.

Election/Restriction

In the previous Office Action (Paper No. 5, 02 April 2003), the claims were restricted as it was understood by the examiner to be directed to a method of administering a polypeptide growth factor. In the interview of 22 May 2003, and in the subsequent amendment, Applicant made it clear that "growth factor" was intended to encompass more than just polypeptides. Diverse agents including cells and genes are also intended by Applicant to be encompassed by the term "growth factor."

Applicant's election with traverse of Group 79, claims 204 and 205, in Paper No. 7 is acknowledged. The traversal is on the ground(s) that examination of all compounds considered by Applicant to fall under the term "growth factor" would not be burdensome. This is not found persuasive because administration of different agents involves search and consideration of the structures of those agents, the method steps involved in administering such agents, and the patient populations selected for treatment with such agents. For example, a reference describing administration of a polypeptide growth

factor does not anticipate, nor necessarily render obvious, a claim to administration of a gene encoding that polypeptide growth factor. Therefore, search and consideration of methods of administering growth factors as defined by Applicant would impose a serious search burden on the USPTO.

Claims 7-203 and 206-235 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

Given the newly submitted claims, and the new understanding regarding what Applicant defines as a "growth factor", clarification of the restriction requirement is deemed appropriate. Therefore, restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 204, 205, 236-240, 247-252 (in part), drawn to method of administering a polypeptide growth factor, a gene product which is a polypeptide, or an extracellular matrix (which often contains polypeptides) to grow a new portion of a pre-existing organ via production of muscle, classified in class 514, subclass 2, for example.

II. Claims 204, 205, 236-242, 247-253 (in part), drawn to methods of administering a growth factor comprising genetic material selected from the group consisting of a portion of a gene, a gene, a gene product which is a polynucleotide (such as mRNA) to grow a new portion of a pre-

existing organ via production of muscle, classified in class 514, subclass 44, for example.

III. Claims 204, 205, 236-239, 243-253 (in part), drawn to methods of administering cells, cellular products and derivatives of cellular products, to grow a new portion of a pre-existing organ via production of muscle, classified in class 424, subclass 520, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons. Groups I-III are directed to methods that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Examination of the method of Group I requires search and consideration of protein therapy. Examination of the method of Group II requires search and consideration of gene therapy. Examination of the method of Group III requires search and consideration of cellular therapy. Each type of method involves very different method steps, and the agents being administered

have very different biochemical and biological properties. For example, a reference describing administration of a polypeptide growth factor does not anticipate, nor necessarily render obvious, a claim to administration of a gene encoding that polypeptide growth factor. The searches required for the three methods are non-overlapping, resulting in a search burden.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements and different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D., whose telephone number is (703) 308-2673.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ECK

Elizabeth C. Kemmerer

August 20, 2003

ELIZABETH KEMMERER
PRIMARY EXAMINER